The Office Action states that Smith and Wong do not expressly teach an outer or second layer comprising a carbonic anhydrase inhibitor that is the same or different as the carbonic anhydrase inhibitor as the carbonic anhydrase inhibitor of the inner drug core. The Office Action additionally states that Heller teaches an ocular insert for the continuous controlled administration of a drug to the eye over a prolonged period of time, wherein concentric layers each comprise particles of drug.

With regard to Applicants' previously presented arguments, the Office Action states that the fact that Smith discloses that reliable release rates over extended periods of time and lack of inflammatory response would be difficult to obtain using an erodible drug delivery system is not a persuasive argument for lack of motivation to combine Smith with Heller because the instant claims do not recite a biodegradable system.

Applicants assert that whether the instant claims require a biodegradable system or not is not relevant. Instead, Applicants are addressing the issue of whether one of skill in the art would have the motivation to combine Smith and/or Wong, which both teach ***non-bioerodible*** devices with the teaching of Heller which teaches only ***bioerodible*** devices to arrive at a device of the pending claims.

Accordingly, Applicants again bring the Examiner's attention to the fact that Smith ***teaches away*** from the use of bioerodible systems for obtaining reliable release rates over extended periods of time. More particularly, Applicants respectfully draw the Examiner's attention to column 6, lines 35-40 ("[t]he use of rapidly dissolving materials or materials highly soluble in eye fluids are to be avoided since dissolution of the wall would affect the constancy of the drug release, as well as the capability of the system to remain in place for a prolonged period of time.") and column 17, lines 13-20 ("[t]hese polymers are biologically inert and are well tolerated by the eye. This is a non-biodegradable system. Although this may be considered a drawback, the reliable release rates over extended periods of time and the lack of inflammatory response would be very difficult to obtain using an erodible drug delivery system.").

Similarly, Applicants assert that Wong discloses devices wherein the outer layer degrades only after all of the drug has been released. More particularly, Applicants respectfully direct the Examiner's attention to column 4, lines 12-16 ("[t]he outer layer material can be made of a polymeric composition and, when in use, is substantially impermeable to body fluids and the drug to be delivered, wherein the influx of the body fluids and the efflux of the drug occurs substantially or entirely through the orifices.") and column 9, lines 43-45 ("[i]n some aspects, the devices may be biodegradable wherein the outer layer degrades ***after the drug has been released*** for the desired duration.").

Applicants assert that neither Smith nor Wong teaches or suggests a device wherein the rate of release of the drug relies on the bioerodibility of the device, and in fact, both Smith and Wong emphasize the importance of non-biodegradability to ensure the desired release profiles. Applicants assert that in view of both Smith and Wong, a person of ordinary skill in the art would be motivated to look to the teachings of non-bioerodible (at least during the term of release) devices in order to obtain linear release of drug.

In contrast, Heller teaches a drug delivery device that erodes in the environment of the eye over a prolonged period of time to dispense the desired amount of drug. Applicants assert that the teachings of Heller are directly contradictory to the teachings of Smith which advise against the use of erodible devices when constant drug release over time is desired. Similarly, Applicants assert that while both Wong and Heller teach bioerodible devices, there is a crucial difference between them, in that the devices of Wong degrade only after the drug has been released, whereas the devices of Heller function such that drug is released as the device degrades.

The Office Action has provided no motivation for one of skill in the art to combine the teaching of Heller (which discloses a second layer comprising a carbonic anhydrase inhibitor as recited in the pending claims) with the teachings of either Smith or Wong. The Office Action merely states that the instant claims are taught by Smith, Wong, and Heller and further that Heller is properly combined with the teachings of Smith and Wong because all of the references teach a controlled or sustained release drug delivery device suitable for ocular insertion.

Applicants disagree and assert that the Examiner is using impermissible hindsight to combine the cited references despite the fact that both Smith and Wong expressly discourage release of drug through a degradation process as taught by Heller. The mere fact that Smith, Wong, and Heller all teach devices suitable for ocular implantation is inadequate to establish a motivation to combine when the express teachings of each of the references are considered. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection based on 35 U.S.C. 103(a). Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (5,902,598) in view of Wong (6,331,313) and further in view of Heller (3,811,444). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The Office Action states that Chen and Wong do not expressly teach an outer or second layer comprising a carbonic anhydrase inhibitor that is the same or different as the carbonic anhydrase inhibitor of the inner drug core. The Office Action additionally states that Heller teaches an ocular insert for the continuous controlled administration of a drug to the eye over a prolonged period of time, wherein concentric layers each comprise particles of drug.

With regard to Applicants' previously presented arguments, the Office Action states that the fact that Chen discloses devices that are insoluble in tear fluid and retain their shape and integrity during the course of therapy is not a persuasive argument for lack of motivation to combine Chen with Heller because the instant claims do not recite a biodegradable system.

Applicants assert that whether the instant claims require a biodegradable system or not is not relevant. Instead, Applicants are addressing the issue of whether one of skill in the art would have the motivation to combine Chen and/or Wong, which both teach ***non-bioerodible*** devices with the teaching of Heller which teaches only ***bioerodible*** devices to arrive at a device of the pending claims.

Accordingly, Applicants again bring the Examiner's attention to the fact that Chen ***teaches away*** from the use of bioerodible systems for obtaining reliable release rates over extended periods of time. More particularly, Applicants respectfully draw the Examiner's attention to column 2, lines 17-24 ("[d]evices formed of polymeric materials that are insoluble in tear fluid retain their shape and integrity during the course of the needed therapy to serve as a drug reservoir for continuously administering a drug to the eye and the surrounding tissues at a rate that is not effected by dissolution or erosion of the polymeric material. Upon termination of the desired therapeutic program, the device is removed from the cul-de-sac."), column 7, lines 5-9 ("[t]he use of rapidly dissolving materials or materials highly soluble in eye fluids are to be avoided since dissolution of the wall would affect the constancy of the drug release, as well as the capability of the system to remain in place for a prolonged period of time."), and column 10, lines 62-64 (the disclosed devices "may remain in the vitreous permanently after treatment is complete.").

Applicants assert that neither Chen nor Wong teaches or suggests a device wherein the rate of release of the drug relies on the bioerodibility of the device, and in fact, both Chen and Wong emphasize the importance of non-biodegradability to ensure the desired release profiles. Applicants assert that in view of both Chen and Wong, a person of ordinary skill in the art would be motivated to look to the teachings of non-bioerodible (at least during the term of release) devices in order to obtain linear release of drug.

In contrast, Heller teaches a drug delivery device that erodes in the environment of the eye over a prolonged period of time to dispense the desired amount of drug. Applicants assert that the teachings of Heller are directly contradictory to the teachings of Chen which advise against the use of erodible devices when constant drug release over time is desired. Similarly, Applicants assert that while both Wong and Heller teach bioerodible devices, there is a crucial difference between them, in that the devices of Wong degrade only after the drug has been released, whereas the devices of Heller function such that drug is released as the device degrades.

The Office Action has provided no motivation for one of skill in the art to combine the teaching of Heller (which discloses a second layer comprising a carbonic anhydrase inhibitor as

recited in the pending claims) with the teachings of either Chen or Wong. The Office Action merely states that the instant claims are taught by Chen, Wong, and Heller and further that Heller is properly combined with the teachings of Chen and Wong because all of the references teach a controlled or sustained release drug delivery device suitable for ocular insertion.

Applicants disagree and assert that the Examiner is using impermissible hindsight to combine the cited references despite the fact that both Chen and Wong expressly discourage release of drug through a degradation process as taught by Heller. The mere fact that Chen, Wong, and Heller all teach devices suitable for ocular implantation is inadequate to establish a motivation to combine when the express teachings of each of the references are considered. Applicants respectfully request reconsideration and withdrawal of this rejection.

Double patenting. Claims 1-3, 14, 16-18, and 20-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 14, 16-18 and 20-21 of copending application 10/762,439.

Pursuant to MPEP 804(I)(B), "[t]he 'provisional' double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that 'provisional' double patenting rejection is the only rejection remaining in at least one of the applications."

Applicants agree to submit a terminal disclaimer at the appropriate time, if necessary.

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. CDSI-P01-040 from which the undersigned is authorized to draw.

Dated: December 21, 2009

Respectfully submitted,

By__/David P. Halstead/_____

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